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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------|---------------------|------------------|
| 10/047,693 | 01/09/2002 | Istvan Bakondi-Kovacs | 2664/47002 | 5182 |
| 26646 | 7590 | 05/22/2006 | EXAMINER | |
| KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004 | | | MARX, IRENE | |
| | | | ART UNIT | PAPER NUMBER |

1651

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|-----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/047,693 | BAKONDI-KOVACS ET AL. | |
| | Examiner | Art Unit | |
| | Irene Marx | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The finality of the rejection of the last Office action is withdrawn in view of the new grounds of rejection *supra*.

Claims 1-27 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The written description and claims in the present specification are confusing and inconsistent in the recitation of the production of “6'-0-carbamoyl tobramycin”. The compound intended appears to be “6”-0-carbamoyl tobramycin”. However, this is not clear from the instant record. Clarification and/or correction is required.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is vague, indefinite and confusing in that the only mineral salt recited in the Markush grouping is zinc phosphate.

Claim 23 lacks antecedent basis on claim 20 for feeding inorganic phosphate during the fermentation. Claim 20 pertains to adjustment of the pH of glucose solution prior to adding to the fermentation medium. Similarly, claim 23 is vague, indefinite and confusing in the recitation “per day”. No antecedent basis is found for this recitation

Claim Rejections - 35 USC § 112

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Claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel strain of *S. tenebrarius* to obtain a specific product. The written description of that strain and the method of isolating is insufficiently reproducible. Therefore, a deposit for patent purposes is required. From the depository numbers it can be seen that the strains are deposited at NCAIM under Budapest Treaty conditions.

For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) **and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.** MPEP 2403.

Additionally, **the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository** and the complete taxonomic description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-6, 9-11, 18-19, 26-27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dinkov *et al.* (Bulgarian patent No. 50996), cited by applicant, but not proffered.

The claims are directed to a fermentation process for producing “6'-0-carbamoyl tobramycin” by regulating constant levels of assimilable carbon and nitrogen sources.

The reference teaches a fermentation process for producing 6"-0-carbamoyl tobramycin by regulating constant levels of assimilable carbon and nitrogen sources.

See, e.g., the claim and page 6, paragraph 1 of the Translation.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dinkov *et al.* taken with Ott *et al.* or Tomita *et al.*

Dinkov *et al.* teaches a fermentation process for producing 6"-0-carbamoyl tobramycin by regulating constant levels of assimilable carbon and nitrogen sources. See, e.g., the claim and page 6, paragraph 1 of the Translation.

The reference differs from the claimed invention in that the specific strains are not recited, in that glutamate is not specifically disclosed as a carbon source and in the use of inorganic salts such as ammonium salts and phosphate. However, each of Ott *et al.* or Tomita *et al.* discloses a fermentation process for the production of 6"-0-carbamoyl tobramycin. See, e.g., Examples. Ott *et al.* discloses a variety of suitable carbon and nitrogen sources, including amino acids such as glutamic acid (See, e.g., page 2, line 55 to page 3, line 13). In addition Tomita *et al.* discloses a similar listing of suitable carbon, nitrogen and inorganic salts such as phosphate. See, e.g., col. 11, lines 7-51.

The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Dinkov *et al.* by feeding additional carbon sources, such as glutamate and using mineral salts such as phosphates as suggested by the teachings of Ott *et al.* and/or Tomita *et al.* for the expected benefit of maximizing the yield of the useful antimicrobial agent 6"-0-carbamoyl tobramycin.

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Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant baldly asserts that "feeding results in fluctuations of the substrate concentrations in the broth, which is not beneficial." It is noted that the Dinkov *et al.* reference feeds at 24 hours in substantially the same manner as applicant. The claims of record do not require a continuous feeding as asserted in the arguments.

Applicant also argues that "Another important difference is that BG 50996 adds a substrate mixture containing both carbon and nitrogen sources preventing maintaining the optimal concentrations of the carbon source and nitrogen source independently during the fermentation". This alleged difference is not in the independent claim and appears only in claim 17. In addition, it is unclear that any data of record substantiates the contentions made in this regard.

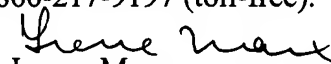
Therefore these arguments fail to persuade.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651